

K070917
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510(K) Summary

Feel Tech

92-4 Haengjung-ri, Gwangdeok-myeon, Cheonan-si,

Choong-nam Korea

Tel. : 82-41-522-2446-8

Fax.: 82-41-522-2449

Contact person: Boo Sool Kim

Date prepared: March 22, 2007

JUN 20 2007

1. Trade Name: Feel-ject Insulin Syringe
Common Name: Insulin syringe
Classification Name: Syringe, piston, product code FMF, Regulation: 880.5860 Class of device: Class II.
2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] :
UltiCare™ Disposable Syringes and Needles K062702 manufactured by Ulti Med Inc.
3. Description of device: The Feel-ject insulin syringe consists of a calibrated hollow barrel which can contain the medication and the distal end of barrel is fixed with needle . The needle cannot be exchanged after assembling because needle is fixed in the barrel nozzle lumen. The plunger and gasket are the same shape as the conventional insulin syringes. The needle cap cover is intended to provide physical protection to the needle tube. The cap is color coded orange, same as equivalent insulin syringes. The syringes are available in 0.5 ml/cc and 1 ml/cc sizes. They are supplied with a sterile fluid path, (EO), non-toxic, and non pyrogenic, for single use only, disposable. The devices operate on the principles of common piston syringes.
4. Intended use: For the injection of U100 insulin.
5. Technological characteristics: The Feel-ject Insulin Syringes and the predicate devices have identical technological characteristics and perform the same way as common piston syringes. These syringes are EO sterilized.
6. Performance: Bench tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Feel Tech
C/O Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

JUN 20 2007

Re: K070917
Trade/Device Name: Feel-Ject Insulin Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 22, 2007
Received: April 3, 2007

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K070917

Indications for Use

510(k) Number (if known):

Device Name: Feel-ject Insulin Syringe

Indications For Use:

The Feel-tech disposable sterile insulin syringes are intended for injection of U100 insulin only.

Prescription Use AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Allen Eraser Anulen 6/6/07
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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